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5. 510(k) SUMMARY of the XE-5000

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: K071967.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4675; FAX: (847) 996-4655 Contact person: Nina Gamperling Date prepared: July 13, 2007
2. Name of Device:	Trade or proprietary name: Sysmex® XE-5000 Common name: Automated Hematology Analyzer. Classification name: Sysmex® XE-Series, Automated Hematology, an Automated Differential Cell Counter (21 CFR 864.5220) is a Class II device. Related Items: CELLPACK™ (Diluent) Product Code: 81GIF CELLSHEATH™ (Diluent) Product Code: 81GIF STROMATOLYSER-FB™ (Lyse) Product Code: 81GGK STROMATOLYSER-4DL™ (Lyse) Product Code: 81GGK STROMATOLYSER-4DS™ (Stain) Product Code: 81KJK STROMATOLYSER-NR™ (Dilent) Product Code: 81GGK STROMATOLYSER- NR™ (Stain) Product Code: 81KJK STROMATOLYSER-IM™ (Lyse) Product Code: 81GGK SULFOLYSER (Lyse) Product Code: 81GGK RET-SEARCH II (Diluent) Product Code: 81GIF RET-SEARCH II (Stain) Product Code: 81KJK XE Calibrators Product Code: 81KSA e-Check (XE) (Control) Product Code: 81JPK Option: Graphic printer Bar code Reader
3. Predicate Method:	Sysmex® XE-2100 Body Fluid (K040073-Cleared March 18, 2004)
4. Device Description:	The Sysmex® XE-5000 is part of the XE-Series instrument line. It is a multi-parameter hematology analyzer intended to perform tests in anti-coagulated blood and body fluids. The instrument consists of three principal units: (1) Main Unit which aspirates, dilutes, mixes and analyzes blood and body fluid samples; (2) Auto Sampler Unit supplies samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system. The XE-5000 is equipped with a Sampler that provides continuous automated sampling for up to 100 tubes. The XE-5000 performs analyses using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser. Particle characterization and identification is based on detection of forward

scatter, fluorescence and adaptive cluster analysis. Using the same reagents as the XE-2100, the XE-5000 automatically classifies cells from blood and body fluids and carries out all processes automatically from aspiration of the sample to outputting the results.

The body fluid analysis mode of the XE-5000 uses the 4DIFF scattergram & the RBC distribution obtained from a specialized analysis sequence to calculate & display the WBC (WBC-BF) counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) counts & percentages, TC-BF (Total Count) & RBC (RBC-BF) counts found in the body fluid.

Analysis results and graphics are displayed on the IPU screen. They can be printed on any of the available printers or transmitted to a Host computer.

5. Intended Use:

Sysmex® XE-5000 is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XE-5000 classifies and enumerates the same parameters as the XE-2100 using whole blood as described below, cord blood for HPC and has a body fluid mode for body fluids. The Body Fluid mode analyzes WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF in body fluids (cerebrospinal fluids (CSF), serous fluids, and synovial fluids with EDTA, as needed).

WBC	White Blood Cell Count
RBC	Red Blood Cell Count
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Cell Volume
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
PLT	Platelet Count
NEUT% / #	Neutrophil Percent and Count
LYMPH% / #	Lymphocyte Percent and Count
MONO% / #	Monocyte Percent and Count
EO% / #	Eosinophil Percent and Count
BASO% / #	Basophil Percent and Count
NRBC% / #	Nucleated RBC Percent and Count
RDW-SD	RBC Distribution Width-SD
RDW-CV	RBC Distribution Width-CV
MPV	Mean Platelet Volume
RET% / #	Reticulocyte Percent and Count
IRF	Immature Reticulocyte
IG% / #	Immature Granulocyte Percent and Count
HPC#	Hematopoietic Progenitor Cells
RET-He	Reticulocyte Hemoglobin
IPF	Immature Platelet Fraction
WBC-BF	WBC count in the body fluid mode analysis.
RBC-BF	RBC count in the body fluid mode analysis.
MN% / #	Percent and number of mononuclear cells within WBC-BF.
PMN%/ #	Percent and number of polymorphonuclear cells in WBC-BF
TC-BF#	The total count including WBC-BF and HF-BF# (the number of particles which appear in a stronger fluorescence area in DIFF scattergram)

6. Substantial equivalence-Similarities and Differences:	Table 1 shows substantial equivalence of the XE-5000 to the XE-2100.
7. Conclusion	The XE-5000 demonstrates substantial equivalence to the XE-2100 Body Fluid application.

Table 1: Substantial Equivalence—Similarities and Difference to XE-2100

	Sysmex XE-2100	Sysmex XE-5000	
	Predicate	**Modification of Predicate**	**Similarity/ Difference**
Intended Use	The Sysmex® XE-2100 Series Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for *in vitro* diagnostic use in clinical laboratories. The body fluid application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid and synovial fluid. Body Fluid Parameters: WBC RBC Capillary Mode Parameters: WBC RBC HGB HCT MCV MCH MCHC PLT RET% / #	Sysmex® XE-5000 is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XE-5000 classifies and enumerates the same parameters as the XE-2100 using whole blood as described below, cord blood for HPC and has a body fluid mode for body fluids. The Body Fluid mode analyzes WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF in body fluids (cerebrospinal fluids (CSF), serous fluids, and synovial fluids with EDTA, as needed). Body Fluid Parameters: WBC-BF RBC-BF MN%/ # PMN% / # TC-BF# Capillary Mode Parameters: WBC RBC HGB HCT MCV MCH MCHC PLT RET% / # NEUT% / # LYMPH% / # MONO% / # EO% / # BASO% / # NRBC% / # IG% / #	Both systems have the same intended use but the XE-5000 has additional capillary and body fluid parameters. 1) Body Fluid Mode has new differential parameters (MN%/# and PMN %/#) and detects WBC and RBC cells at a lower level than the XE-2100. The body fluid mode is used on body fluid samples with RBC counts greater than 0.003 x 10^6/ul, WBC counts greater than 0.01 x 10^3/ul for CSF and 0.030 x 10^3/ul for other body fluids and a WBC differential (MN%/# and PMN %/#) for samples with WBC counts. 2) Capillary mode on whole blood includes differential with NRBC#/% & IG#/%. 3) Addition of WBC-D parameter on whole blood.
Methodology	The XE-2100 performs analyses using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser. The RF/DC detection method	The XE-5000 performs analyses using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser. The RF/DC detection method detects the size of the	Both systems use the same methodology.

	detects the size of the cells by changes in direct-current resistance & the density of the cell interior by changes in radio-frequency resistance. Cells pass through the aperture of the detector surrounded by sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the cells passing through the flow cell. The forward scattered light is received by the photodiode, & the lateral scattered light & lateral fluorescent light are received by the photo multiplier tube. This light is converted into electrical pulses, thus making it possible to obtain cell information.	cells by changes in direct-current resistance & the density of the cell interior by changes in radio-frequency resistance. Cells pass through the aperture of the detector surrounded by sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the cells passing through the flow cell. The forward scattered light is received by the photodiode, & the lateral scattered light & lateral fluorescent light are received by the photo multiplier tube. This light is converted into electrical pulses, thus making it possible to obtain cell information.	
Reagents	CELLPACK™ (Diluent) CELLSHEATH™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) STROMATOLYSER-NR™ (Diluent) STROMATOLYSER-NR™ (Stain) STROMATOLYSER-IM™ (Lyse) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)	CELLPACK™ (Diluent) CELLSHEATH™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) STROMATOLYSER-NR™ (Diluent) STROMATOLYSER-NR™ (Stain) STROMATOLYSER-IM™ (Lyse) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)	The XE-2100 and the XE-5000 use the same reagents.
Quality Control/ Calibrator	*e*-Check—3 levels XE Calibrator (X Cal)	*e* -Check (XE) —3 levels XE Calibrator (X Cal)	The XE-2100 and the XE-5000 use the same calibrator, but the XE-5000 uses a specific quality control material, *e* -Check (XE), that has been previously cleared.
Software/ Hardware Differences	The XE-pro software was added to the original XE-2100 in order to include additional master programs (HPC, IG, RET, IPF) and perform Body Fluid analysis.	The XE-5000 uses the same XE-pro software and includes additional masters (HPC, IG, RET, IPF) along with a Body Fluid mode in the initial standard software model.	The XE-5000 performs the same as the XE-2100 with the HPC, IG, RET and IPF masters along with a Body Fluid mode that has additional parameters (TC-BF, MN%/# and PMN %/#). The XE-5000 capillary mode includes the differential, NRBC and IG parameters.
Specimen Type	Random whole blood and body fluid samples	Random whole blood and body fluid samples.	Both systems use the same specimen types.
Throughput	Approximately 113-150 samples/hour depending on the mode used.	Approximately 113-150 samples/hour depending on the mode used.	Both systems have the same throughput.
Equivalency Data:	Performance was initially established in XE-2100 510(k) submission (K992875) & then additional masters/parameters were submitted in subsequent submissions:	Performance of the XE-5000 whole blood mode is the same as the XE-2100 with additional masters. The Body Fluid mode of the XE-5000 has additional parameters. Comparison of the	Data consisting of carryover, linearity, accuracy and reproducibility was collected to show performance to the manufacturer's specification for the Body Fluid mode. This

	XE-2100/HPC (K020496), XE-2100/IG (K032039), XE-Body Fluid (K040073), XE-2100 RET/He (K050589), XE-2100/IPF (K051199).	XE-5000 body fluid mode to the XE-2100 demonstrated excellent correlation.	analysis supports the claim that the XE-5000 Body Fluid mode is substantially equivalent to the XE-2100 Body Fluid.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2007

Sysmex America, Inc.
C/O Nina M. Gamperling
One Nelson C. White Parkway
Mundelein, Illinois 60060

Re: k071967
Trade/Device Name: Sysmex XE-5000
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Hematology Analyzer
Regulatory Class: Class II
Product Code: GKZ
Dated: July 13, 2007
Received: July 17, 2007

Dear Ms. Gamperling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071967

Device Name: Sysmex® XE-5000, Automated Hematology Analyzer

Indications For Use:

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071967

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)